REMARKS/ARGUMENTS

Claims 42, 73, 76, and 80 have been amended and claims 43-47, 53, 61, 66, 74-75, and 77-80 have been cancelled without prejudice to or disclaimer of the subject matter encompassed thereby. Applicants expressly reserve the right to file continuing applications or take other such appropriate measures to seek protection of the inventions encompassed by any cancelled subject matter.

Claims 42 and 73 have been amended to incorporate the limitations from previously presented claims 45, 50, and 62 that the targeting molecule be covalently linked via a peptide bond to an antigen combining site of at least one biological agent and where the targeting molecule comprises a J chain or portion thereof encoded by nucleotides 1-213 of SEQ ID NO:8. Claim 42 has been amended to remove reference to wherein the targeting molecule comprises an amino acid sequence comprising SEQ ID NOS: 114, 115, 116, 117, 118, or 119. Claim 73 has been amended to remove reference to wherein the targeting molecule comprises at least domain 2 of a J chain. Claim 76 has been amended to depend from claim 73. Accordingly, no new matter has been added by way of claim amendment.

These claim amendments were not presented earlier as Applicants earnestly believe that the previously presented claims recited patentable subject matter. The Examiner is respectfully requested to enter these claim amendments to further prosecution or to place the application in better condition for appeal.

Claims 42, 52, 54-60, 62-65, 67-69, 73, and 76 are pending in the application. Reconsideration of these claims is respectfully requested in view of the aforementioned claim amendment and the following remarks. The Examiner's comments in the Office Action are addressed below in the order set forth therein.

Election of Species

Applicants note that the Examiner acknowledges the election of species in the present case made in the paper filed December 18, 2002. Claims 42 and 73 have been amended to be directed to a targeting molecule comprising a J chain encoded by nucleotides 1-213 of SEQ ID NO:8 covalently linked via a peptide bond to an antigen combining site. All of the remaining

claims depend directly or indirectly from either claim 42 or claim 73. Accordingly, the present claims reflect the prior filed election of species.

Maintained Double-Patenting Rejections

Applicants note that the Examiner has maintained obviousness-type double patenting rejections of claims 42-48, 52-69, and 73-77 as being unpatentable over the claims of co-pending U.S. Patent Application Nos. 08/782,481 and 10/062,467, as well as issued U.S. Patent No. 6,440,419. As stated in the Office Action Response dated July 22, 2005, when the Examiner deems the claims of the present application to be allowable except for these rejections, Applicants will file a terminal disclaimer in the present application.

The Rejections of the Claims Under 35 U.S.C. §112, First Paragraph Should Be Withdrawn

The Examiner maintains the rejection of claims 73, 74, 76, and 77 under 35 U.S.C. §112, First Paragraph, as containing subject matter that the Examiner contends is not described in the specification in a way as to reasonably convey to one of skill in the art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner also maintains the rejection of claims 73, 74, 76, and 77 under 35 U.S.C. § 112, First Paragraph, as containing subject matter that the Examiner contends is not described in the specification in a way as to reasonably enable one of skill in the art to make or use the claimed invention. Due to the similarity of these two rejections they will be addressed together below. Claims 74 and 77 have been cancelled. These rejections are respectfully obviated with respect to the remaining claims for the reasons described below.

For both rejections, the Examiner points out that although Applicants' previous arguments in the Office Action Response dated July 22, 2005 were based upon a stated amendment of claims 73, 74, 76, and 77 to incorporate specific SEQ ID NOS, no such amendments were made. Based upon this, the Examiner states that there are no structural or functional limitations to the portion of the J chain in claims 73, 74, 76, and 77 and that it cannot be ascertained which of the SEQ ID NOS in the dependent claims constitute the minimal structure required to generate an SC-binding site. Furthermore, the Examiner states that one of

skill in the art would have to resort to undue experimentation to determine the minimal structure required to generate an SC-binding site.

Applicants have corrected their error by presently amending claim 73 to include the limitation that the targeting molecule comprise a J chain or portion thereof encoded by nucleotides 1-213 of SEQ ID NO:8. Remaining claim 76 has been amended to depend from claim 73 and therefore also contains this limitation. Accordingly, Applicants respectfully submit that this rejection under 35 U.S.C. §112, First Paragraph, has been obviated and should be withdrawn.

The Rejection of the Claims Under 35 U.S.C. §§102(b) and (e) Should Be Withdrawn

The Examiner maintains the rejection of claims 73, 74, 76, and 77 under 35 U.S.C. §102(b) as being anticipated by Wallner *et al.* (WO 92/16622). The Examiner maintains the rejection of claims 73, 74, 76, and 77 under 35 U.S.C. §102(e) as being anticipated by Capra (U.S. Patent No. 6,063,905). Due to the similarity of these two rejections they will be addressed together below. Claims 74 and 77 have been cancelled. These rejections are respectfully obviated with respect to the remaining claims for the reasons described below.

Wallner *et al.* disclose fusion proteins containing a portion of LFA-3 containing a functional CD2-binding domain fused to at least a portion of the Fc region of an immunoglobulin. The Fc region is preferably limited to the hinge region of the CH2 and CH3 domains. In addition, Wallner *et al.* disclose multimeric forms of LFA-3-Ig fusion proteins generated by using those Fc regions, or portions thereof, of Ig molecules that are usually multivalent, e.g., IgM pentamers and IgA dimers. Wallner *et al.* state that a J chain polypeptide may be necessary to form and stabilize IgM pentamers and IgA dimers.

Capra discloses an IgA antibody consisting essentially of a VH domain fused to a first IgA1 Cα3 domain including a tailpiece, a VL domain fused to a second IgA1 Cα3 domain including a tailpiece, and a J chain, wherein the VL and VH domains constitute an antigen or hapten recognition site. The invention may further be defined as the dimers of the described minimal IgA antibodies formed by disulfide bonds between the monomers and the J chains and across the tailpieces. Capra therefore discloses a molecule comprising a J chain covalently

linked via a peptide bond to an antigen combining site that does not contain any of $C_H1\alpha$, $C_H2\alpha$, $C_H3\alpha$ and C_L.

For both rejections, the Examiner points out that although Applicants' previous arguments in the Office Action Response dated July 22, 2005 were based upon a stated amendment of claims 73, 74, 76, and 77 to incorporate specific SEQ ID NOS, no such amendments were made. Applicants have corrected their error by presently amending claim 73 to include the limitation that the targeting molecule comprise a J chain or portion thereof encoded by nucleotides 1-213 of SEQ ID NO:8. Remaining claim 76 has been amended to depend from claim 73 and therefore also contains this limitation.

To anticipate a claim, a reference must teach every element of the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Neither Wallner *et al.* nor Capra teach use of a targeting molecule that comprises a J chain or portion thereof encoded by nucleotides 1-213 of SEQ ID NO:8. Accordingly, neither Wallner *et al.* nor Capra meet all of the limitations of any of the pending claims, including claims 73 and 76.

Because neither the Wallner *et al.* nor the Capra references teach each and every element of any of the pending claims, Applicants respectfully submit that these rejections under 35 U.S.C. §§102(b) and (e) have been obviated and should be withdrawn.

The Rejection of the Claims Under 35 U.S.C. §103(a) Should Be Withdrawn

The Examiner maintains the rejection of claims 73, 74, 76, and 77 under 35 U.S.C. §103(a) as being obvious in view of Max & Korsmeyer (1985) *J. Exp. Med.* 161:832-849 in combination with Janknecht & Nordheim (1992) *Gene*, 121:321-324. The rejection is respectfully obviated for the reasons described below.

The Examiner points out that although Applicants' previous arguments in the Office Action Response dated July 22, 2005 were based upon a stated amendment of claims 73, 74, 76, and 77 to incorporate specific SEQ ID NOS, no such amendments were made. There, Applicants were responding to arguments presented by the Examiner in the Office Action dated March 22, 2005. The Examiner stated that Max & Korsmeyer teaches an isolated nucleic acid molecule

encoding the amino acid sequence of SEQ ID NOS:125, 130, 131, 133, 135, and AsnLys. The Examiner further stated that Janknecht & Nordheim teaches the production of eukaryotic proteins in a functional state, using eukaryotic expression systems employing vectors designed to express either N- or C-terminally histidine tagged proteins in eukaryotic cells. Based upon these references, the Examiner stated that it would have been obvious to one of skill in the art to recombinantly express the human J chain nucleic acid molecule as taught by Max & Korsmeyer with a His tag as taught by Janknecht & Nordheim.

Applicants have corrected their claim amendment error by presently amending claim 73 to include the limitation that the targeting molecule comprise a J chain or portion thereof encoded by nucleotides 1-213 of SEQ ID NO:8. Remaining claim 76 has been amended to depend from claim 73 and therefore also contains this limitation.

One of the necessary elements for establishing a *prima facie* case of obviousness is that the prior art reference(s) must teach or suggest all the claim limitations. MPEP §2143, citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Max & Korsmeyer and Janknecht & Nordheim, individually or in combination, do not teach or suggest that nucleotides 1-213 of SEQ ID NO:8, are particularly important for binding to or facilitating binding to an epithelial basolateral factor. Furthermore, the Examiner has not presented any evidence that one of skill in the art, reading the combined references, would be motivated to focus on nucleotides 1-213 of SEQ ID NO:8. Therefore, claims 73 and 76 are not rendered obvious in light of the combination of Max & Korsmeyer and Janknecht & Nordheim.

Because the combination of Max & Korsmeyer and Janknecht & Nordheim does not teach or suggest all the claim limitations of claims 73 and 76, a *prima facie* case of obviousness has not been established and the rejection under 35 U.S.C. §103(a) should be withdrawn.

CONCLUSION

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. §§ 112, First Paragraph, 102(b) and (e), and 103(a) are overcome. Accordingly, Applicants submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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CERTIFICATION OF FACSIMILE TRANSMISSION
I hereby certify that this paper is being facsimile transmitted to the US Patent and Trademark Office at Fax No. (571) 273-8300 on the date shown below.

Lynda-Jo Pixley — May 1, 2006 (Date)